149 Cong. Rec. S15882-03 at S15884 (Nov. 25, 2003) (remarks of Sen. Kennedy during consideration of the Conference Report on the MMA).

Second, in § 1102, Congress restructured the 180-day exclusivity period granted to a generic company when it was the first to file an ANDA challenging a patent (known as paragraph IV certification) and it established that its product did not infringe. Congress now requires the generic company to forfeit exclusivity if it does not begin producing the product within 75 days of an event resolving the patent dispute, either through settlement, court decision or dismissal. This eliminated the incentive under the old law for name-brand and generic manufacturers to "park" the exclusivity period granted to first-to-apply generics through an agreement not to market the generic thereby blocking all other generic companies from coming to the market. 149 Cong. Rec. S15670-03 at S15746 (Nov. 24, 2003)(remarks of Sen. Schumer during consideration of the Conference Report for the MMA).

Third, in § 1101(a)(C) of Title XI, Congress clarified that generic manufacturers could bring a declaratory judgment action to "seek a prompt resolution of . . . patent issues" where the patent holder has not initiated a patent infringement action within 45 days after receiving notice of a patent challenge. 149 Cong. Rec. S15882-03 at S15884-5 (Nov. 25, 2003)(remarks of Sen. Kennedy during consideration of the Conference Report for the MMA). This is an essential provision because it is the legal proceedings surrounding resolution of the patent issues which trigger all of the other threshold events under the Federal Food, Drug and Cosmetic Act that determines when and whether a generic can come to market. Leaving the initiation of such proceedings solely to the discretion of the patent holder

allows the patent holder to control when competition could commence, and to defer commencement as long as possible.

B. Congress Intended That Courts Should Exercise their Declaratory Judgment Jurisdiction to the Limits of their Article III Power.

The language, structure, and history of § 1101(a)(C) reveal Congress' intent that courts favor declaratory judgment jurisdiction to promptly resolve patent issues that might delay generic competitors to brand name drugs. While general declaratory judgment authority for federal courts was already authorized under 28 U.S.C. § 2201 to resolve "a case of actual controversy," § 1101(a)(C) of the MMA expressly provides for "a civil action to obtain patent certainty" where the patent owner or brand name manufacturer has not brought suit within 45 days of the generics' challenge to the patent. Section 1101(a)(C)(i), "Declaratory Judgment Absent Infringement" corrects an imbalance created by Hatch-Waxman provisions which allowed the brand name drug company to extend patent life and control competition by controlling the timing of infringement/invalidity disputes. Section 1101(d) provides that "the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction . . . [over] a declaratory judgment that such patent is invalid or not infringed." 35 U.S.C. § 271(e)(5). The new provisions simply make clear what the old law implied: that courts should resolve patent disputes whether or not the patent holder has initiated suit. The Joint Explanatory Text to the Conference Agreement on the law explains that:

> The conferees expect that courts will find jurisdiction, where appropriate, to prevent an improper effort to delay infringement litigation

> between generic drug manufacturers and pioneer drug companies. . . .The conferees expect the courts to examine as part of their analysis the particular policies served by the Hatch-Waxman Act. . . .

H.R. Conf. Rep. No. 108-391, at 836 (2003). Congress made explicit that the courts should exercise their authority to resolve patent disputes to the limit of their Article III power specifically recognizing that an ANDA has been filed with a paragraph iv certification and that the patentee has not filed an infringement suit -- the very circumstances of this case -- in determining jurisdiction. *Id.*[5/] As Senator Kennedy recognized, the "clarification of a generic applicants right to bring a declaratory judgment action is crucial to ensuring prompt resolution of patent issues, which is essential to achieve our goal of speeding generic drugs to market." 149 Cong. Rec. S15882-03 at S15885 (Nov. 25, 2003).

As of August 1, 2005, generic drug manufactures have 303 pending ANDAs containing paragraph IV patent certifications, certifying that their generic version will not infringe a brand name manufacturer's listed patent or that such patent is invalid.[6/] While we do not know the factual background on each of these patent disputes and the various incentives the patent holder has to promptly bring suit or not, we do know well enough that this scenario results in concrete

---

[5/] Section § 1101(d), codified at 35 U.S.C. § 271(e)(5). The constitutional authority of the federal courts to decide declaratory judgment actions where there has been a paragraph IV ANDA certification was discussed extensively in the Congressional Record. 149 Cong. Rec. S15751-55 (Nov. 24, 2003).

[6/] U.S. Food & Drug Administration, Center for Drug Evaluation and Research, Paragraph IV Patent Certifications As of August 1, 2005 *at* www.fda.gov/cder/ogd/ppiv.htm.

controversies where an affirmative remedy is needed. *See, In re Cardizem CD Antitrust Litigation,* 332 F.3d 896 (6th Cir. 2003); *Valley Drug Co. v. Geneva Pharm. Inc.,* 344 F.3d 1294 (11th Cir. 2003); *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 166 F.3d 740 (E.D. N.Y. 2001). The sooner the invalidity or non-infringement can be conclusively established for any of these drugs, the sooner consumers benefit from lower cost generics. But if a court does not resolve the issue of patent validity because the patent holder does not initiate suit, it effectively blocks generic entry.[7/]

In this case, there has been an assertion by the patent holder that it intends to exclude all those who would seek to copy its product, made in the form of a representation to the government by its listing its patent in the FDA's Orange book.[8/] There is a challenge to the legitimacy of those patent

---

[7/] *See* 149 Cong. Rec. S15885-86 (Nov. 25, 2003)(Sens. McCain, Schumer and Kennedy discussing courts exercising jurisdiction over declaratory judgments actions involving paragraph IV ANDA certifications and introducing letter from the Federal Trade Commission to Sen. Hatch stating "[w]ithout the right to seek a declaratory judgment, a subsequent generic applicant that develops a clearly non-infringing product cannot trigger the first generic applicant's exclusivity because the subsequent generic applicant will not be sued for patent infringement by the brand-name company.")

[8/] *See* 21 U.S.C. § 355(b)(1) (requiring that a new drug applicant "shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which *a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.*")(emphasis added). *See also Minnesota Mining and Mfg. v. Barr Labs.*, 289 F.3d 775, 791(Fed. Cir. 2002)(Gajarsa, J. concurring in the judgment) (stating a declaratory judgment suit is available for ANDA filers not sued by the NDA patentee within the 45-day period and "[t]he two acts of (1) a patentee listing a patent in the

claims made by a would-be competitor, who has prepared to come to market, made in the form of a certification to the FDA that the generic does not infringe the listed patent. The parties' legal positions are in conflict; both businesses have taken steps averring that the other has no right to do what it seeks to do. Despite this, the Federal Circuit found there was no actual controversy because Teva does not have a reasonable apprehension that Pfizer will bring suit imminently if Teva attempts to market the generic. *Teva Pharmaceuticals, Inc. v. Pfizer*, 395 F.3d 1324 (Fed. Cir. 2005.

As the following discussion makes clear, where generic competition is likely to result in the brand name drug losing substantial market share, the economics of the situation compels the conclusion that Teva not only has a reasonable apprehension of suit, but that it has every basis to believe that Pfizer will bring a patent infringement action at a time designed to protect its lucrative product as long as possible. If the drug patent existed in a vacuum, the court's decision below might make some sense. However, under the legal framework of drug approval, and the realities of the pharmaceutical industry's profitability and pricing structure, there is more than a theoretical question before the court.

C. Pharmaceutical Economics Demonstrate Why Congress Sought to Encourage the Exercise of Declaratory Judgment Jurisdiction.

Legislation was badly needed: "[a]s the Federal Trade Commission has shown, however, in recent years both

---

Orange Book through the filing of a NDA, and (2) a generic manufacturer filing an ANDA, together meet the case or controversy requirement so as to allow a declaratory judgment action of non-infringement.")

brand-name and generic drug companies have exploited certain aspects of the Hatch-Waxman Act to delay generic competition." 149 Cong. Rec. S15882-03 at S15884 (Nov. 25, 2003) (remarks of Sen. Kennedy during consideration of the Conference Report on the MMA). According to IMS Health (a large pharmaceutical market research firm), the generic drug share of the total number of prescriptions rose steadily from 18.6 % in 1984 to 42.4 % in 1996, but declined in 1998 to 41.3 %. Michie I. Hunt, BlueCross BlueShield Association, *Prescription Drug Costs: Federal Regulation of the Industry* 51 (2000)[Hunt (BlueCross)]. Generic drugs' market share as a percentage of total dollar sales slipped from a high of 12.2% in 1995 to 8.6% in 1998. *Id.* The significance of the decline in generic penetration is a loss for consumers because the greatest price reduction for a particular drug only comes with competition among multiple generic competitors. The more generic versions of the same drug that are on the market, the lower the price consumers pay for a generic version, regardless of which generic company is marketing the drug product.[9/] Studies of pricing and market share of innovator drugs and their generic counterparts confirm that substantial savings to the consumer occur as soon as the generic is substituted for the brand name

---

[9/] David A. Balto, *Pharmaceutical Patent Settlements: The Antitrust Risk*, 55 Food & Drug L.J. 321, 325-6; *see also* Keith B. Leffler & Cristofer I. Leffler, *Want to Pay a Competitor to Exit the Market? Settle a Patent Infringement Case: An Argument for Per Se Condemnation of Payments by the Patent Holder*, ABA Economics Committee Newsletter 35 (Spring 2002); Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, Chapter 3 (July 1998) *available at* http://www.cbo.gov/showdoc.cfm?Index=655&sequence=0 [CBO]; Henry Grabowski and John Vernon, *Longer Patents for Increased Generic Competition in the US: The Waxman-Hatch Act After One Decade*, 10 PharmacoEconomics 110, 115 (1996); Hunt (BlueCross), *supra*, at 61.

drug, and that even more savings occur over time as other generic versions of the drug enter the market.[10/] Because of this, the name brand manufacturer has a strong incentive to limit the number of generic competitors by forestalling any challenge to its patent monopoly. The fewer the competitors, the less the cost differential, and therefore, the name brand keeps a greater market share. But if courts decline to exercise jurisdiction where name brand manufacturers delay resolution of patent disputes, Congresses' intent to balance the playing field between name brand and generic drug manufactures in order to bring down escalating prescription drug costs will be frustrated.

CONCLUSION

The decision over the justiciability over prescription drug patent disputes is a public policy matter impacting many people's health and welfare because it directly affects the cost of pharmaceuticals. AARP urges the Court to grant the petition for a writ of certiorari because this important question of federal law should be settled by this Court.

[10/] Bureau of Competition & of Policy Planning, Federal Trade Commission, *In the Matter of 180-Day Generic Drug Exclusivity for Abbreviated New Drug Applications* 4-5 (Nov. 4, 1999) *available at* http://www.ftc.gov/be/v990016.htm; CBO, "Competition Among Generic Drugs"; Grabowski, *supra*, at 115; *see also In re Cardizem CD*, 200 F.R.D. 326, 327-8 (E.D. Mich. 2001).

September 7, 2005

Respectfully submitted,

Sarah Lenz Lock*
Bruce Vignery
AARP Foundation Litigation

Michael Schuster
AARP
601 E Street, NW
Washington, DC 20049
(202) 434-2060
Counsel for *Amicus Curiae*
AARP
*Counsel of Record

FILED
SEP 7 - 2005
OFFICE OF THE CLERK
SUPREME COURT, U.S.

No. 05-48

IN THE

Supreme Court of the United States

Teva Pharmaceuticals USA, Inc.,
Petitioner,

v.

Pfizer, Inc.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

BRIEF *AMICUS CURIAE* OF THE GENERIC PHARMACEUTICAL ASSOCIATION IN SUPPORT OF PETITIONER

Thomas C. Goldstein
(Counsel of Record)
Amy Howe
Kevin K. Russell
GOLDSTEIN & HOWE, P.C.
4607 Asbury Pl., NW
Washington, DC 20016
(202) 237-7543

September 7, 2005

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

TABLE OF CONTENTS

TABLE OF CONTENTS i
TABLE OF AUTHORITIES ii
INTEREST OF *AMICUS CURIAE* 1
STATEMENT OF THE CASE 1
I. Background to the Statutory Scheme 1
II. The Instant Litigation And The Lower Court Rulings 4
REASONS FOR GRANTING THE WRIT 7
I. The Decision Below Is Contrary To This Court's Precedents Defining The "Case Or Controversy" Required By Article III Of The U.S. Constitution And Conflicts With The Precedent Of Other Circuits 9
II. The Question Presented Is Vitally Important To Pharmaceutical Competition 16
CONCLUSION 20

TABLE OF AUTHORITIES

Cases

Aetna Life Insurance Co. v. *Haworth*, 300 U.S. 227 (1937) 11

Apotex v. *Pfizer*, 125 Fed. Appx. 987 (CAFC Apr. 11, 2005), *vacating and remanding as moot Torpharm, Inc.* v. *Pfizer*, No. 03-CV-990, 2004 U.S. Dist. LEXIS 11,930 (D. Del. June 28, 2004) 19

Apotex v. *Pfizer*, No. 04-CV-02539 (S.D.N.Y. Apr. 1, 2004), appeal pending, No. 05-1199 (CAFC) 18

Arrowhead Industrial Water v. *Ecolochem*, 846 F.2d 731 (CAFC 1988) 10, 15

Bio-Technology Gen. Corp. v. *Duramed Pharms., Inc.*, 174 F. Supp. 2d 229 (D.N.J. 2001), rev'd, 323 F.3d 1356 (CAFC 2003) 17

BP Chems. v. *Union Carbide Corp.*, 4 F.3d 975 (CAFC 1993) 3, 15

Cardinal Chemical Co. v. *Morton International*, 508 U.S. 83 (1993) 10

Chesebrough-Pond's, Inc. v. *Faberge, Inc.*, 666 F.2d 393 (CA9 1982) 12

Dr. Reddy's Laboratories v. *Pfizer*, No. 03-726, 2003 U.S. Dist. LEXIS 24,351 (D.N.J. July 8, 2003) 18

Eli Lilly & Co. v. *Medtronic*, 496 U.S. 661, reh'g denied, 497 U.S. 1047 (1990) 16

EMC Corp. v. *Norand Corp.*, 89 F.3d 807 (CAFC 1996) 14

Festo Corp. v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002), *vacating and remanding* 234 F.3d 558 (CAFC 2000) 8

Geneva Pharm. v. *GlaxoSmithKline*, 213 F. Supp. 2d 597 (E.D. Va. 2002), aff'd, 349 F.3d 1373 (CAFC 2003) 17

Holmes Group v. *Vornado Air Cir. Sys.*, 535 U.S. 826 (2002), *vacating and remanding* 13 Fed. Appx. 961 (CAFC 2001) 8, 11

Janssen Pharm. N.V. v. *Eon Labs*, 374 F. Supp. 2d 263 (E.D.N.Y. 2004), aff'd, 134 Fed. Appx. 425 (CAFC 2005) 17

Maryland Cas. Co. v. *Pacific Coal & Oil Co.*, 312 U.S. 270 (1941) 6

Merck KGaA v. *Integra Lifesciences I*, 125 S. Ct. 2372 (2005), *vacating and remanding* 331 F.3d 860 (CAFC 2003) 8

Mutual Pharm. Co. v. *Pfizer*, No. 03-CV-1116, 2004 U.S. Dist. LEXIS 4846 (D.D.C. Mar. 24, 2004) 19

Mylan v. *Merck & Co.*, No. 05-cv-1416 (SHR) (M.D. Pa.) 19

Purdue Pharma L.P. v. *Endo Pharmaceuticals*, 410 F.3d 690 (CAFC 2005) 17

Raines v. *Byrd*, 521 U.S. 811 (1997) 15

Sallen v. *Corinthians*, 273 F.3d 14 (CA1 2001) 13

Sherwood Medical Indus., Inc. v. *Deknatel, Inc.*, 512 F.2d 724 (CA8 1975) 12

Steel Co. v. *Citizens for a Better Env't*, 523 U.S. 83 (1988) 9

United Christian Scientists v. *Christian Science Bd. of Directors, First Church of Christ, Scientist*, 829 F.2d 1152 (CADC 1987) 12

Statutes

21 U.S.C. 355(b)(1) 2, 13

21 U.S.C. 355(c)(2) 2, 13

21 U.S.C. 355(j)(2)(A) 1

21 U.S.C. 355(j)(5)(B)(iii) 2, 5

21 U.S.C. 355(j)(5)(B)(iv) 2

21 U.S.C. 355(j)(5)(C) 3

35 U.S.C. 271(e)(2) 2, 13

35 U.S.C. 271(e)(5) 4, 9, 15

Other Authorities

AARP, Prescription Drug Costs And The Role Of Generic Drugs (Oct. 1, 2002), available at http://assets.aarp.org/rgcenter/health/rx_generic.pdf 20

Conf. Rep. No. 108-391 (2003) 3

Dep't of Health and Hum. Servs. Task Force on Drug Importation, REPORT ON PRESCRIPTION DRUG IMPORTATION (Dec. 2004), available at http://www.hhs.gov/importtaskforce/Report1220.pdf (visited Sept. 7, 2005) 20

Generics Key To Cost Control, UPI, May 19, 2005 20

Generics: FDA Announces Measures To Improve Generic Drug Access, DRUG WEEK, Mar. 26, 2004 20

Nat'l Inst. For Health Care Management, *A Primer: Generic Drugs, Patents, and the Pharmaceutical Marketplace* (June 2002), available at http://www.nihcm.org/GenericsPrimer.pdf 20

Steven Findlay, *Easy Way To Cut Costs Of Drugs: Generics*, USA TODAY, May 13, 2004, at 23A 20

INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae Generic Pharmaceutical Association ("GPhA") represents over 120 companies that manufacture more than ninety percent of all affordable prescriptions dispensed in the United States each year, accounting for more than one billion prescriptions annually. GPhA accordingly has a significant interest in the proper construction of the so-called Hatch-Waxman scheme, which Congress enacted to speed the marketing of generic drugs while protecting the legitimate patent rights of brand-name drug companies.

STATEMENT OF THE CASE

I. Background to the Statutory Scheme

In the 1984 Hatch-Waxman Amendments to the federal patent and drug laws, Congress sought to ameliorate two substantial obstacles to the efforts of generic pharmaceutical manufacturers to compete against brand manufacturers. First, Congress created a streamlined process for FDA approval of generic drug products through which generic manufacturers may submit an Abbreviated New Drug Application (ANDA) demonstrating the bioequivalence of the so-called "pioneer" product and its generic equivalent. 21 U.S.C. 355(j)(2)(A).

Second, Congress adopted a scheme to expedite the litigation of patent disputes. Generic manufacturers, which seek to compete with a brand product already in the marketplace, often face the prospect of a patent infringement suit by the brand company. Such a suit, if successful, could result in debilitating liability if the generic drug were marketed but later found to infringe the patent. Thus, as Congress well knew, in cases of genuine doubt, generic manufacturers may decline to

---

[1] Pursuant to S. Ct. R. 37.6, *amicus* states that no counsel to a party authored this brief in whole or in part and that no person other than *amicus curiae* and its members made a financial contribution towards the preparation and submission of the brief. Letters reflecting the consent of the parties have been lodged with the Court.

launch their less-expensive products, even if the brand company's patent claims would ultimately have been rejected.

Congress accordingly created a statutory mechanism to permit early resolution of potential patent infringement claims against a new generic drug prior to its marketing. Under Hatch-Waxman, brand manufacturers must identify any patent for which "a claim of patent infringement could reasonably be asserted" against the maker of a generic equivalent. 21 U.S.C. 355(b)(1), (c)(2). FDA publishes that patent information in its "Orange Book." In turn, a generic manufacturer's submission of an ANDA challenging the validity, enforceability, or infringement of an Orange Book-listed patent constitutes a statutory act of patent infringement, vesting the federal courts with subject matter jurisdiction over an infringement suit. 35 U.S.C. 271(e)(2).

Congress contemplated that these provisions would resolve patent disputes soon after the ANDA is filed. To encourage generic companies to avail themselves of these new statutory provisions, Congress amended the statutory scheme in other ways as well. For example, Congress created an incentive for brand companies to bring a patent infringement claim promptly after learning of the ANDA filing. If a brand company initiates patent litigation within forty-five days of receiving notice of an ANDA applicant's challenge to its patent, FDA must defer approval of the generic product for thirty months. 21 U.S.C. 355(j)(5)(B)(iii).

Congress also encouraged generic drug development by providing that the owner of the first ANDA containing a challenge to a listed patent receives a 180-day period of marketing exclusivity against other generic competitors. 21 U.S.C. 355(j)(5)(B)(iv). Specifically, the FDA must defer approval of later-filed applications until 180 days after the earlier of two specified dates. *Ibid.* Particularly relevant here, a later generic applicant can trigger the start of this 180-day period by obtaining a judgment declaring the listed patent invalid, unenforceable, or not infringed. *Ibid.*

The Hatch-Waxman provisions were only a partial success, however. Through various tactics, brand manufacturers could use the exclusivity period granted to first ANDA filers to block later generic competitors out of the marketplace for years. Despite the thirty-month stay that would result if a brand company initiated suit within the forty-five-day Hatch-Waxman window, brand companies often had a substantial incentive to refrain from instituting litigation before the generic drug was brought to market. A judicial determination could backfire by producing a finding of non-infringement that would trigger the start of the 180-day exclusivity period, thereby allowing more generic companies to enter the market sooner. Moreover, declining to institute patent litigation could leave in place a cloud of patent uncertainty that delayed generic market entry longer than a patent suit itself.

District courts have often ruled that declaratory judgment actions must be dismissed for failure to satisfy the Federal Circuit's "reasonable apprehension" test. Even though Congress clearly contemplated that generic manufacturers would be permitted to resolve patent claims through a declaratory judgment suit against the patentee, the Federal Circuit, which has exclusive jurisdiction over patent appeals, has held that a declaratory judgment suit was impermissible unless the plaintiff itself faced a reasonable apprehension of suit from the patentee. *E.g.*, *BP Chems.* v. *Union Carbide Corp.*, 4 F.3d 975, 978 (1993). That rule rested on that court's "pragmatic" concern that merely obtaining a patent should not subject the patentee to litigation. *Ibid.*

In response to these continuing impediments, Congress enacted further legislation in 2003 "to prevent an improper effort to delay infringement litigation between generic drug manufacturers and pioneer drug companies." Conf. Rep. No. 108-391, at 836 (2003). As amended, the legislation provides that, if the brand manufacturer does not bring suit within the forty-five-day Hatch-Waxman period, the generic competitor may itself institute a declaratory judgment action. 21 U.S.C. 355(j)(5)(C). Recognizing its power to remove the Federal

Circuit's prudential standing barrier, Congress further provided that the district courts would have jurisdiction over such a suit to the fullest "extent consistent with the Constitution." 35 U.S.C. 271(e)(5).

II. The Instant Litigation And The Lower Court Rulings

1. This case arises from petitioner Teva's intention to market a generic equivalent to respondent Pfizer's antidepressant Zoloft® (the trade name for the drug sertraline). As is relevant here, Pfizer listed in the Orange Book two patents that it claimed could reasonably be asserted against a competitor to Zoloft®. According to Pfizer, one expires in 2006; the other (known as the "'699 patent") expires in 2010.

In 2002, Teva filed an ANDA for a generic equivalent to Zoloft®. The ANDA stated that Teva intended to begin marketing as soon as Pfizer's first patent expired in 2006. Teva maintained that the '699 patent either would not be infringed or was invalid.

Teva's ANDA submission constituted a statutory act of infringement of the '699 patent. Pfizer did not, however, sue Teva. Pfizer knew that its refusal to bring suit would impede and delay competition from Teva in two ways. First, it would leave a cloud of patent uncertainty, threatening Teva with the prospect of massive patent liability if it brought its drug to market before the '699 patent expired in 2010.

Second, by avoiding a resolution of the patent dispute, Pfizer prevented FDA from approving Teva's product until at least 180 days *after* Pfizer's first patent expired in 2006. This distinct, categorical approval prohibition arose from a side agreement between Pfizer and another generic manufacturer, Ivax, which had filed the first ANDA for sertraline and thus had a right to generic exclusivity for its sertraline product. Pfizer had sued Ivax for patent infringement in response to the latter's ANDA, but then settled in exchange for a share of the revenues from Ivax's sales. Teva could avoid or limit this additional 180-day delay, however, if it secured a court judgment that Pfizer's '699 patent was either invalid or not in-

fringed prior to the expiration of Pfizer's first patent. See 21 U.S.C. 355(j)(5)(B)(iii).

2. To remove the cloud of patent uncertainty over its product, and to avoid the delay in FDA approval occasioned by the Ivax application and agreement with Pfizer, Teva brought this declaratory judgment action against Pfizer. The district court, however, deemed itself bound to hold that Teva's claim was not ripe because Teva itself faced no imminent suit from Pfizer. Pet. App. 37a-47a. The district court notably did not dispute that Pfizer was refusing to sue precisely to limit generic competition. Instead, it concluded that this fact ironically deprived Teva of standing, for "Pfizer's self-interest in" deferring the resolution of the patent dispute only "makes the prospects of [it bringing] a lawsuit against Teva (or anyone else) even more remote." *Id.* 46a.

3. Teva appealed, supported by the Federal Trade Commission as *amicus curiae*.[2] The FTC emphasized the "important role" this case would play "in furthering competitive pharmaceutical markets and in lowering health care cost[s]." FTC Panel Br. 3. "The issue has important ramifications for the operation of Hatch-Waxman because such a declaratory judgment" may be "the *only* means by which a generic drug maker may be able to" bring a competing product to market. *Ibid.* (emphasis added). The FTC explained: "If the district court's decision is upheld, it will enable first generic applicants and brand-name drug manufacturers to delay substantially entry by other generic firms, and indeed by *any* generic firm (including one that has done a better job of designing around the patent), into the marketplace for a drug." *Id.* 3-4 (emphasis in original).

A divided panel of the Federal Circuit nonetheless affirmed. Pet. App. 1a-36a. The panel majority acknowledged this Court's prior holding that the existence of an "actual con-

---

[2] The FTC's brief (FTC Panel Br.) is available at http://www.ftc.gov/ogc/briefs/teva_v_pfizer.pdf.

troversy" sufficient to bring a declaratory judgment action depends on "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." Pet. App. 12a (quoting *Maryland Cas. Co.* v. *Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

Teva's brief demonstrated that there is indeed a concrete controversy between it and Pfizer. For example, by listing its patents in the Orange Book, Pfizer had declared that Zoloft® was protected by the '699 patent, whereas Teva contends that the '699 patent did not preclude its market entry. Pfizer had moreover previously invoked that very patent to sue Ivax when it sought to introduce a generic equivalent for Zoloft®. Notwithstanding that Teva's ability to bring its product to market was directly precluded by Pfizer's conduct, Pfizer had refused Teva's request for a covenant not to sue.

Despite these undisputed facts, the Federal Circuit concluded that its so-called "reasonable apprehension" test is a constitutional threshold for bringing a declaratory judgment action. Pet. App. 20a. The court held that a declaratory judgment action is justiciable only if there is "an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit." *Id.* 13a. Indeed, the plaintiff must "demonstrate that it has a reasonable apprehension of *imminent* suit." *Id.* 16a.

The panel majority concluded that Teva could not meet this rigorous standard because the very point of Teva's claim is that Pfizer seeks to *avoid* a court adjudication of the dispute: "Significantly, Teva virtually concedes that Pfizer will not bring immediate suit for infringement of the '699 patent. According to Teva, Pfizer does not wish to expose the patent to the possibility of a noninfringment or invalidity determination * * *." Pet. App. 16a. The majority found it irrelevant that Teva was injured by this state of affairs:

> The fact that Teva is disadvantaged from a business standpoint * * * and the fact that Pfizer's decision not to sue Teva creates an impediment to Teva's removing that disadvantage are matters separate and distinct from whether an Article III controversy exists between Teva and Pfizer. The injury about which Teva complains is the product of the Hatch-Waxman scheme and the fact that Pfizer has acted in a manner permitted under that scheme. *It is not the product of a threat of suit by Pfizer. That is the problem that Teva faces in seeking to establish district court jurisdiction.*

Id. 26a (emphasis added). It continued:

> [I]n order to rule in Teva's favor, we would have to hold that the Article III requirement of an actual controversy is satisfied, not because Teva is under an imminent threat of suit by Pfizer, but because the combined circumstances of the Hatch-Waxman scheme and Pfizer's lawful conduct under that scheme have created a situation in which Teva finds itself at a competitive disadvantage * * *. Those circumstances do not amount to an actual controversy between Teva and Pfizer, however.

Ibid.

4. Teva petitioned for rehearing en banc, again supported by the FTC as *amicus curiae*.[3] The petition was denied over the dissenting votes of three judges who issued two dissenting opinions. See Pet. App. 48a.

REASONS FOR GRANTING THE WRIT

The petition for certiorari should be granted for several reasons. The court of appeals' decision is flatly contrary to this Court's precedents identifying the "case or controversy"

---

[3] The FTC's brief (FTC En Banc Br.) is available at http://www.ftc.gov/ogc/briefs/050208teva.pdf.